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10/758,261	01/16/2004	Gerhard Moersdorf	06478.1497	5706

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EXAMINER
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GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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09/19/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/758,261

Applicant(s)

MOERSDORF ET AL.

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-35 is/are pending in the application.
- 4a) Of the above claim(s) 24-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Acknowledgments***

1. This office action is in response to the reply filed on 7/9/2007.
2. In the reply, the Applicant amended claims 1, 4, 6, and 22 and cancelled claim 5.
3. Additionally, the Applicant amended the Specification to obviate the previous objection to the Specification.
4. Additionally, the Applicant amended the claim language to obviate the previous objection to the drawings by removing claimed subject matter that was not shown in the drawings.
5. Claims 24-35 were previously withdrawn.
6. Thus, claims 1-4, 6-23 are pending for examination.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4, 6-10, 13, 19-22 are is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon (5879336) in view of Kulle (4346704).
9. Brinon discloses a sterile sheath (13; Fig 4) comprising: a sealed casing (13; wherein Webster's defines a seal as "something that confirms, ratifies, or makes secure" and "a closure that must be broken to be opened" and thus, the casing (13) is sealed by the cover (20) such that the cartridge is secured inside the casing;

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additionally, see Response to Arguments discussion below) made of plastic, the casing including an output connection piece (13), wherein the output connection piece includes a valve (2, Fig 1-3) whose direction of flow is exclusively from an injection syringe to the exterior, wherein an interior (Fig 1-8) of the sterile sheath is configured to receive the entire injection syringe, and wherein the output connection piece is configured to be connected to the syringe (Fig 3, 11, 10); wherein an outer region (12a) of the output connection piece is configured to receive a medical device, and wherein the medical device is one of a needle, an adapter, a multiport valve, and an infusion bottle (col 2, Ins 50-52); wherein the sealable casing is at least partially transparent (col 3, Ins 24-28); wherein the valve is one of a non-return valve (2); wherein the output connection piece includes a cone-shaped recess (10, 9; Fig 3) configured to receive a syringe cone of the injection syringe; wherein the output connection piece includes a hollow body (13) configured to receive a cylindrical section of the injection syringe; wherein the hollow body has a cylindrical shape (13; Fig 1-8); wherein the output connection piece includes, on an end opposite from the valve, an annular plate (22); the sealable casing further comprising a pressure pocket (20) configured to connect to the output connection piece; further comprising a sealing element (Fig 1, 6-8) to seal between the output connection piece and the pressure pocket; wherein the output connection piece includes a section configured as a cone (inner annular projection inside luer lock 12a – Figs 1, 3) to receive a cone-shaped recess of the medical device; wherein the output connection piece and the medical device are connected by means of a swivel closure (12a); wherein the swivel closure is a screw thread (12a).

10. However, Brinon does not expressly disclose wherein the output connection piece includes as least on radial discharge aperture sealable by means of an elastic ring element, wherein the elastic ring element is a tubular ring element, which encloses a portion of the output connection piece.

11. Kulle teaches that it is known to have the output connection piece includes as least on radial discharge aperture sealable by means of an elastic ring element, wherein the elastic ring element is a tubular ring element, which encloses a portion of the output connection piece (48, 40; Fig 2) for the purpose of a one-way valve with low residual volume so that critical medications may be administered in precise quantities with less waste while also providing higher flow rates at lower pressures (col 2, Ins 17-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the uni-directional valve as taught by Brinon with the unidirectional valve being a radial discharge aperture sealable by means of a tubular elastic ring element as taught by Kulle for the purpose of providing a one-way valve with low residual volume so that critical medications may be administered in precise quantities with less waste while also providing higher flow rates at lower pressures (col 2, Ins 17-24).

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Kulle. Brinon in view of Kulle discloses the invention substantially as claimed except for expressly disclose the annular plate having an oval aperture. At the time the invention was made, it would have been an obvious matter of design choice to a person

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of ordinary skill in the art to have the annular plate have an oval aperture because the Applicant has not disclosed that having an annular plate with an oval aperture provides an advantage, is used for a particular purpose, or solves a stated problem.

Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the annular plate having a circular aperture of Brinon in view of Kulle because the annular plate performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify Brinon in view of Kulle to obtain the invention as specified in claim 11.

13. Claim 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Kulle. Brinon in view of Kulle discloses the invention substantially as claimed except for expressly disclosing the output connection piece being formed by injection molding. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the output connection piece as taught by Brinon in view of Kulle with an output piece made by injection molding since it was well known in the art that injection molding is used to provide rigid plastic parts for medical devices.

14. Claims 14-16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Kulle. Brinon in view of Kulle discloses the invention substantially as claimed except for expressly disclosing wherein the pressure pocket is formed by injection molding, by a dipping method, or by means of extrusion-blow molding. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the pressure pocket formed by injection

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molding, by a dipping method, or by means of extrusion-blow molding because the Applicant has not disclosed that having the pressure pocket formed by injection molding, by a dipping method, or by means of extrusion-blow molding provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the pressure pockets of Brinon in view of Kulle because the pressure pockets perform substantially the same function in substantially the same manner.

Furthermore, claims 14-16 are directed to a product by process and it has been held that the patentability of the product does not depend on its method of production (see MPEP 2112.02). Therefore, it would have been an obvious matter of design choice to modify Brinon in view of Kulle to obtain the invention as specified in claims 14-16.

15. Claim 17-18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Kulle in further view of Riuli (4713060). Brinon in view of Kulle additionally discloses wherein the shoulder piece includes a snap-in lug (22) configured to engage a snap-in lug (20) on an annular plate of the output connection piece.

However, Brinon in view of Kulle does not expressly disclose wherein the pressure pocket includes a shoulder film-like plastic hood. Riuli teaches that it is known to have wherein the pressure pocket includes a shoulder film-like plastic hood (40) for the purpose of providing a flexible cover flexible enough to allow movement of the plunger while acting as a barrier for helping to blow the transfer of fluid and particulate matter between the chamber and the environment (Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

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pressure pocket as taught by Brinon in view of Kulle with the film-like plastic as taught by Riuli for the purpose of providing a flexible cover flexible enough to allow movement of the plunger while acting as a barrier for helping to block the transfer of fluid and particulate matter between the chamber and the environment (Abstract).

16. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brinon in view of Riuli in further view of Kulle. Brinon and Riuli disclose the invention substantially as claimed except for wherein the output connection piece further includes at least one radial discharge aperture sealable by means of an elastic ring element. Kulle teaches that it is known to have at least one radial discharge aperture (48) sealable by means of an elastic ring element (40) for the purpose of providing uni-directional flow with a low residual valve size (see Disclosure of Invention). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the one-way valve as taught by Brinon and Riuli with the radial aperture and elastic ring valve as taught by Kulle for the purpose of providing uni-directional flow with a low residual valve size (see Disclosure of Invention).

### ***Response to Arguments***

17. Applicant's arguments filed 7/9/2007 have been fully considered but they are not persuasive.

18. The Applicant argues that:

- i. Brinon does not disclose a case 13 that is sealed as the cover 20 includes opening 19 and pushbutton 18 is pierced to admit air into the reservoir. (Remarks, pg 11-12)



19. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the sealed casing is an airtight seal) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, the Examiner notes that Webster's defines a seal as "something that confirms, ratifies, or makes secure" and "a closure that must be broken to be opened". Brinon discloses a casing (13) that is sealed by a cover (20) such that the cartridge is secured inside the casing and such that the cover must be removed or opened to remove the cartridge. Thus, Brinon discloses a sealed casing.

### ***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

